DON HUMAN RESEARCH PROTECTION OFFICIAL (HRPO) CHECKLIST FOR EXTRAMURAL RESEARCH

- Please complete the following checklist for all extramural research involving human subjects and submit it with all applicable documents to the HRPO for review. The HRPO will return an HRPO determination along with the checklist and documents to the Program Officer for inclusion in the PR package to be sent to the Contracting Officer.
- If the contract award includes multiple protocols, an HRPO checklist should be completed for each protocol.
- If the research involves special populations/categories, please complete the Additional Checklist and submit it to the HRPO as well.

Program Manager:	Michael Simpson
■ New Award	☐ Existing Award #
Performer Name:	Curators of the University of Missouri on behalf of UMKC
Proposal Title:	Equity-Forward Workforce Development Pipeline for Naval STEM Superiority
Proposal Principal Investigator:	Daniel McIntosh

☑ New Protocol ☐ Amendment Protocol #_____

☐ Continuing Review Protocol (every year): original protocol # _____

1. Research Involving Human Subjects ☑ **YES** ☐ **NO**

(If Yes Skip to #2 and complete checklist – If No Complete #1 and sign last page of checklist)

YES	N/A	
☐	☐	The proposal has been provided.
☐		Not Research Involving Human Subjects Determination Letter
☐		Application / Form submitted to HRPP/IRB to make the Determination

2. Performer Contract and Assurance/Addendum Information

YES	N/A	
☑	☐	The proposal has been provided.
☐	☑	Subcontractors are engaged in the human subject research. *If yes, please list:*
☑		Federal Wide Assurance (FWA) documentation has been provided by the Performer (including documents for Subcontractors, if applicable). (The response to this question cannot be N/A.) *Documents must be current (i.e., not expired) In addition other documents also could include an Individual Investigator Agreement and/or an Institutional Agreement for IRB Review.*

3. Exemption Determination or Institutional Review Board (IRB) Approval

YES	N/A	
☐	☑	An IRB approval letter has been provided by the IRB(s). (A Yes response is required unless an exemption letter is provided.)
☑	☐	If an exemption determination letter has been provided, the letter lists a 32 CFR 219.104(d) exemption category number and rationale statement. (A Yes response is required if an exemption is claimed.) *The rationale must correspond with the exemption category cited. Determinations may be made by Performers IRB Chairs, Vice Chairs, IRB Administrators or designated HRP persons, but not the PI. Special requirements apply for research involving children and research involving prisoners is not eligible for exemption.*
☑		The IRB approval or exemption is current. (The response to this question cannot be N/A.)

4. IRB Risk Level Determination for Non-Exempt Research

☐	Minimal Risk *Expedited Review is only available for minimal risk research. If research has been subject to Expedited Review it should be at minimal risk level.*
☐	Greater than Minimal Risk

5. IRB-Approved Protocol for Non-Exempt Research

YES	N/A	
☐		An IRB-approved protocol has been provided. (The response to this question cannot be N/A.)
☐		The PI listed on the protocol is correct and the work reviewed by the IRB is the same as the work/effort to be performed under the contract SOW (The response to this question cannot be N/A.)
☐	☐	If the approved protocol is greater than minimal risk, the protocol includes use of an independent medical monitor). (A Yes response is required if the research is greater than minimal risk.) *Medical monitors may include a range of healthcare providers.*

6. IRB-Approved Informed Consent Form for Non-Exempt Research

YES	N/A	
☐	☐	The protocol includes an IRB-approved informed consent form or IRB-approved informed consent script (32 CFR 219.116 and 32 CFR 219.117).
☐	☐	If no consent form or script is included, the protocol or other IRB provided documentation includes an explanation (32 CFR 219.116 and 32 CFR 219.117).

Note: Informed consent must be addressed

7. HRP Training

YES	N/A	
☑		Documentation of completion of research ethics training by the PI has been provided (DoDI 3216.02 Enclosure 3 para 6.a.6(a)2). (The response to this question cannot be N/A.)

8. Special Subject Populations or Research

If yes, complete and attach the Additional HRPO Checklist for Special Populations and Special Research Categories.

Yes	No		Yes	No	
☐	☑	Military or DoD civilian personnel	☐	☑	Indigenous Tribes
☐	☑	Children	☐	☑	Classified research
☐	☑	Pregnant women, human fetuses, or neonates	☐	☑	Research including severe or unusual physical or psychological intrusions
☐	☑	Prisoners, Prisoners of War, or Captured or Detained Personnel	☐	☑	Research likely to bring media attention; potentially or inherently controversial topic
☐	☑	Experimental subjects who do not have the capacity to provide informed consent for themselves due to age, condition or otherwise	☐	☑	Research with test/investigational articles including drugs, devices, biologics/vaccines; clinical trial research
☐	☑	Subjects in foreign country	☐	☑	Research involving testing the effects of nuclear, biological, or chemical agents

Program Officer Review

To the best of my knowledge the information included in this checklist accurately describes the research effort that I am sponsoring.

SIMPSON.MICHAEL.M.1468441450 Digitally signed by SIMPSON.MICHAEL.M.1468441450 Date: 2021.05.03 21:17:20 -04'00'

PO Signature _____ Date _____

HRPO Review

MAY.SUZANNE.B.1504976587 Digitally signed by MAY.SUZANNE.B.1504976587 Date: 2021.05.04 10:41:15 -04'00'

HRPO Signature _____ Date 04 May 21